Position Statement: EU MDR [2017/745] Supporting Documentation

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STATEMENT: EU MDR Documentation Support for Single-Use Non-Sterile Components distributed by Qosina Corp.

To our valued customers,

As a responsible distributor of single-use, non-sterile components, we strive to support our customers in the preparation of regulatory filings to ease the incorporation of our components into your regulated medical devices.

The EU MDR has increased the documentation requirements for finished devices and Qosina has been actively working to support these enhanced requirements. We have reviewed the EU MDR 2017/745 Annex II – Technical Documentation requirements and created this guide to help you understand the documentation which may provide applicable information for each section. This guide has been prepared generically for all components and we have mapped the potentially relevant requirements for the supporting documentation. The supporting documentation in this guide may or may not be applicable based on the nature of the component or your intended use. This document is meant as a guide only. The scope of the information requested from our suppliers is summarized below. While we strive to provide comprehensive support documentation, it should be noted that not all requested information is made available by every supplier. All product documentation Qosina maintains is made available for download at www.qosina.com/resources or on the product page. If the available documentation does not meet your requirements, please contact your Qosina representative to request a specific document or select alternative components.

Qosina maintains an ISO 13485 Certified Quality Management System. We have strict processes to evaluate, qualify, audit, and approve each supplier to ensure they employ professional quality management, documentation control, change control, and manufacturing controls. All changes to the product or manufacturing process of which we are notified are documented and managed in our change control/change notification process. All customers who have sampled or purchased an item in the past 7 years are notified of changes.

Scope of information requested from suppliers & maintained in an ISO 13485 controlled database:

- **Item Description & Measurements**
- **2D Drawings**
- **3D CAD Model**
- **Bill of Materials**
- **Resin Trade Names & Grades**
- **CAS #'s**
- **Material Safety Data Sheets**
- **Material Technical Data Sheets**
- **Colorant information**
- **Mold Release, Lubricant & Manufacturing Aids**
- **Country of Manufacture**
- **Storage Conditions**
- **Pre/Post Sterilization Shelf Life**
- **Manufacturing Environment Classification**
- **Manufacturing Facility Quality Management System**
- **Semi-Annual REACH (SVHC) Declaration**
- **California Proposition 65**
- **Conflict Minerals**
- **Semi-Annual EU MDR CMR / ED Declaration (10.4.1)**
- **RoHS Declaration**
- **Product & Packaging Latex**
- **Plasticizers**
- **USP <87> Biocompatibility**
- **USP <88> Biocompatibility**
- **USP <661.1>**
- **E.P. 3.1.X**
- **ISO 10993 Biocompatibility**
- **Pyrogens**
- **Sterilization Compatibility**
- **Animal Derived Ingredients**
- **Human Derived Material Statement**
- **Medicinal Substances Statement**
- **Particulates & Nanomaterials**
- **N-Nitrosamines**
- **Residual Solvents (ICH Q3C)**
- **Elemental Impurities (ICH Q3D)**
- **ISO 80369-X**

For simplicity, the information above is summarized in our item-specific Specification Summary Sheets.

Kindest regards,

Jack Arendash, Director of Quality, Qosina Corp.

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Annex II Section	Generally Applicable Requirements SOURCE: EU MDR [2017/745]	Documentation Guidance / Position Statement
1.0 DEVICE DESCRIPTION AND SPECIFICATION, INCLUDING VARIANTS AND ACCESSORIES		
1.1	1.1. Device description and specification (a) product or trade name and a general description of the device including its intended purpose and intended users; (d) principles of operation of the device and its mode of action, scientifically demonstrated if necessary; (j) a general description of the key functional elements, e.g. its parts/components (including software if appropriate), its formulation, its composition, its functionality and, where relevant, its qualitative and quantitative composition. Where appropriate, this shall include labelled pictorial representations (e.g. diagrams, photographs, and drawings), clearly indicating key parts/components, including sufficient explanation to understand the drawings and diagrams; (k) a description of the raw materials incorporated into key functional elements and those making either direct contact with the human body or indirect contact with the body, e.g., during extracorporeal circulation of body fluids; (l) technical specifications, such as features, dimensions and performance attributes, of the device and any variants/configurations and accessories that would typically appear in the product specification made available to the user, for example in brochures, catalogues and similar publications.	1.1 Device Description 1.1. (a) See Qosina Item # & description. Intended use is excluded. 1.1.(d) (j) Qosina Item description. 1.1 (k) See Qosina specification Summary Sheet and associated material documents such as TDS & SDS. 1.1 (l) See Item 2D drawing and/or CAD model
1.2	1.2. Reference to previous and similar generations of the device (a) an overview of the previous generation or generations of the device produced by the manufacturer, where such devices exist; (b) an overview of identified similar devices available on the Union or international markets, where such devices exist.	1.2 (a) See any available change notifications for reference to any previous generations of the component

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3.0 DESIGN AND MANUFACTURING INFORMATION		
3.0	(a) information to allow the design stages applied to the device to be understood; (b) complete information and specifications, including the manufacturing processes and their validation, their adjuvants, the continuous monitoring and the final product testing. Data shall be fully included in the technical documentation; (c) identification of all sites, including suppliers and sub-contractors, where design and manufacturing activities are performed.	3.0 (b)(b)(c) Qosina's Quality Management System is certified to ISO 13485:2016. Our procedures require continuous evaluation of our suppliers to ensure they consistently provide products that meet our and our customer's requirements and conform with applicable regulatory requirements. The required and ongoing evaluation of our suppliers includes routine audits of the manufacturing facility QMS. The scope of these audits is based on the requirements of ISO 13485:2016 including but not limited to Sections 7.3 and 7.5 of the standard; Product & Service Provision (manufacturing processes, controls, product validation), Design & Development, as well as product changes. Qosina suppliers who are compliant with the requirements of ISO 13485:2016, therefore, meet the applicable requirements of this section. Please see Specification Summary Sheet for confirmation of the manufacturing facility's Quality Management System.

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4.0 GENERAL SAFETY AND PERFORMANCE REQUIREMENTS (Annex I GSPR) CHAPTER II. REQUIREMENTS REGARDING DESIGN AND MANUFACTURE		
4.0	10. Chemical, physical and biological properties 10.1. Devices shall be designed and manufactured in such a way as to ensure that the characteristics and performance requirements referred to in Chapter I are fulfilled. Particular attention shall be paid to: (a) the choice of materials and substances used, particularly as regards toxicity and, where relevant, flammability; (b) the compatibility between the materials and substances used and biological tissues, cells and body fluids, taking account of the intended purpose of the device and, where relevant, absorption, distribution, metabolism and excretion; (f) the mechanical properties of the materials used, reflecting, where appropriate, matters such as strength, ductility, fracture resistance, wear resistance and fatigue resistance;	10.1(a) See Material TDS, SDS, REACH & RoHS Declarations. 10.1.(b) See Specification Summary Sheet for Biocompatibility information. 10.1.(f) See Material TDS
4.0	10.2. Devices shall be designed, manufactured and packaged in such a way as to minimise the risk posed by contaminants and residues to patients, taking account of the intended purpose of the device, and to the persons involved in the transport, storage and use of the devices. Particular attention shall be paid to tissues exposed to those contaminants and residues and to the duration and frequency of exposure.	See the specification summary sheet for cleanroom classification and information regarding manufacturing aids and mold release agents.
4.0	10.4. Substances 10.4.1. Design and manufacture of devices Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks posed by substances or particles, including wear debris, degradation products and processing residues, that may be released from the device. Devices, or those parts thereof or those materials used therein that: — are invasive and come into direct contact with the human body, — (re)administer medicines, body liquids or other substances, including gases, to/from the body, or — transport or store such medicines, body fluids or substances, including gases, to be (re)administered to the body, shall only contain the following substances in a concentration that is above 0,1 % weight by weight (w/w) where justified pursuant to Section 10.4.2: (a) substances which are carcinogenic, mutagenic or toxic to reproduction ('CMR'), of category 1A or 1B, in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council (1), or (b) substances having endocrine-disrupting properties for which there is scientific evidence of probable serious effects to human health and which are identified either in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council (2) or, once a delegated act has been adopted by the Commission pursuant to the first subparagraph of Article 5(3) of Regulation (EU) No 528/2012 of the European Parliament and the Council (3), in accordance with the criteria that are relevant to human health amongst the criteria established therein.	See Semi-Annual EU MDR Declaration
4.0	10.6. Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks linked to the size and the properties of particles which are or can be released into the patient's or user's body, unless they come into contact with intact skin only. Special attention shall be given to nanomaterials.	See the Specification Summary Sheet for information regarding manufacturing cleanroom classification and nanomaterials.
4.0	11.6. Devices intended to be sterilised shall be manufactured and packaged in appropriate and controlled conditions and facilities.	See the Specification Summary Sheet for information regarding manufacturing cleanroom classification.
4.0	12. Devices incorporating a substance considered to be a medicinal product and devices that are composed of substances or of combinations of substances that are absorbed by or locally dispersed in the human body.	See the Specification Summary Sheet for information regarding medicinal substances.

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4.0	13. Devices incorporating materials of biological origin 13.1. For devices manufactured utilising derivatives of tissues or cells of human origin which are non-viable or are rendered non-viable covered by this Regulation in accordance with point (g) of Article 1(6), the following shall apply: (a) donation, procurement and testing of the tissues and cells shall be done in accordance with Directive 2004/23/EC; (b) processing, preservation and any other handling of those tissues and cells or their derivatives shall be carried out so as to provide safety for patients, users and, where applicable, other persons. In particular, safety with regard to viruses and other transmissible agents shall be addressed by appropriate methods of sourcing and by implementation of validated methods of elimination or inactivation in the course of the manufacturing process; (c) the traceability system for those devices shall be complementary and compatible with the traceability and data protection requirements laid down in Directive 2004/23/EC and in Directive 2002/98/EC.	See the Specification Summary Sheet for information regarding materials of biological origin.
4.0	13.2. For devices manufactured utilising tissues or cells of animal origin, or their derivatives, which are non-viable or rendered non-viable the following shall apply: (a) where feasible taking into account the animal species, tissues and cells of animal origin, or their derivatives, shall originate from animals that have been subjected to veterinary controls that are adapted to the intended use of the tissues. Information on the geographical origin of the animals shall be retained by manufacturers; (b) sourcing, processing, preservation, testing and handling of tissues, cells and substances of animal origin, or their derivatives, shall be carried out so as to provide safety for patients, users and, where applicable, other persons. In particular safety with regard to viruses and other transmissible agents shall be addressed by implementation of validated methods of elimination or viral inactivation in the course of the manufacturing process, except when the use of such methods would lead to unacceptable degradation compromising the clinical benefit of the device; (c) in the case of devices manufactured utilising tissues or cells of animal origin, or their derivatives, as referred to in Regulation (EU) No 722/2012 the particular requirements laid down in that Regulation shall apply.	See the Specification Summary Sheet for information regarding materials of biological origin.
4.0	13.3. For devices manufactured utilising non-viable biological substances other than those referred to in Sections 13.1 and 13.2, the processing, preservation, testing and handling of those substances shall be carried out so as to provide safety for patients, users and, where applicable, other persons, including in the waste disposal chain. In particular, safety with regard to viruses and other transmissible agents shall be addressed by appropriate methods of sourcing and by implementation of validated methods of elimination or inactivation in the course of the manufacturing process.	See the Specification Summary Sheet for information regarding materials of biological origin.
4.0	14. Construction of devices and interaction with their environment 14.1. If the device is intended for use in combination with other devices or equipment the whole combination, including the connection system shall be safe and shall not impair the specified performance of the devices. Any restrictions on use applying to such combinations shall be indicated on the label and/or in the instructions for use. Connections which the user has to handle, such as fluid, gas transfer, electrical or mechanical coupling, shall be designed and constructed in such a way as to minimise all possible risks, such as misconnection.	See the Specification Summary Sheet for information regarding ISO 80369-X as appropriate.
4.0	14.6 Any measurement, monitoring or display scale shall be designed and manufactured in line with ergonomic principles, taking account of the intended purpose, users and the environmental conditions in which the devices are intended to be used.	See the drawing for any component with a measuring function as appropriate.
4.0	14.7. Devices shall be designed and manufactured in such a way as to facilitate their safe disposal and the safe disposal of related waste substances by the user, patient or other person. To that end, manufacturers shall identify and test procedures and measures as a result of which their devices can be safely disposed after use. Such procedures shall be described in the instructions for use.	See REACH Statement
4.0	15. Devices with a diagnostic or measuring function 15.1. Diagnostic devices and devices with a measuring function, shall be designed and manufactured in such a way as to provide sufficient accuracy, precision and stability for their intended purpose, based on appropriate scientific and technical methods. The limits of accuracy shall be indicated by the manufacturer.	See the drawing for any component with a measuring function as appropriate.

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4.0	15.2. The measurements made by devices with a measuring function shall be expressed in legal units conforming to the provisions of Council Directive 80/181/EEC (1).	See the drawing for any component with a measuring function as appropriate.
4.0	20.4. Terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies which the user or other person has to handle, shall be designed and constructed in such a way as to minimise all possible risks.	See the Specification Summary Sheet for information regarding ISO 80369-X as appropriate.
4.0	20.5. Errors likely to be made when fitting or refitting certain parts which could be a source of risk shall be made impossible by the design and construction of such parts or, failing this, by information given on the parts themselves and/or their housings. The same information shall be given on moving parts and/or their housings where the direction of movement needs to be known in order to avoid a risk.	See the Specification Summary Sheet for information regarding ISO 80369-X as appropriate.

Notes:

1. Qosina products are not qualified, marketed, or offered as CE Marked EU-regulated medical devices. Adherence to the requirements and qualification of the critical functions of the finished device is the responsibility of the Device Manufacturer.
2. For brevity, all requirements not considered to be generally applicable to non-sterile components have been omitted from this table.

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